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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/824,964	04/15/2004	G. Ian Rowlandson	140822IT (5024-00138)	7468

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EXAMINER	
MORALES, JON ERIC C	
ART UNIT	**PAPER NUMBER**
3766	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/06/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/824,964	ROWLANDSON ET AL.	
	Examiner	Art Unit	
	Jon-Eric C. Morales	3766	

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 February 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *15 April 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/24/2004 and*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/20/2007 has been entered.

Claim Objections

1. Claim 1 is objected to because of the following informalities: In the last line of claim 1 it reads outputting a signature pattern of the patent. Examiner understands that patent should be replaced with patient. Appropriate correction is required.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1. Claims 1-3 and 6-12 +20 are rejected under 35 U.S.C. 102(e) as being anticipated by Peel, III et al. (US Patent No. 6647287).

Regarding claims 1, 2, 6, 9, 11, and 20 Peel, III discloses a cardiovascular monitor that comprises of a method that analyzes aortic blood pressure. It does this by measuring and acquiring continuous radial or ulnar blood pressure with a tonometer or a blood pressure sensor (implant device data) inserted in an artery (column 28 lines 63-67, column 29 lines 1-10). The method also entails measuring and acquiring a plethysmographic blood pressure (non-implant patient data), from the patient via their finger, using one or more pulse oximeters (column 28 lines 50-62). The values from the implant in the radial or ulnar artery are synchronized with the plethysmographic blood pressure values found from a finger sensor. By use of a mathematical model (algorithm) for correlation (column 16 lines 60-67, column 17 lines 1-3, column 18 lines 32-40), a patient-specific aortic blood pressure waveform (signature pattern) is the result from the patients' implant and non-implant cardiac data acquired (column 7 lines 37-40). The patient specific aortic blood pressure waveform is disclosed for diagnosis of cardiovascular condition and treatment of the patient (Column 1 lines 6-10).

With respect to claims 7, 8, and 10, Peel, III also discloses multiple storage devices that save blood pressure data of a patient and the data of the mathematical model for later usage (column 29 lines 33-36). As well as a display monitor to show representations of any of the patient data. The data provided can include any of the implantable blood pressure sensors or ECG data (column 29 lines 36-39). The disclosed display monitor is to visually assist in the diagnosis of the condition and effects of the treatments for a patient. Peel, III discloses a selection of choices, including

ECG data, plethysmograph, and any one of the pulse oximeter measurements for use in the mathematical models (column 34 lines 33-37).

Regarding claims 3 and 12, Peel, III further shows a time reference is measured for a start of each blood pressure pulse in the ECG measurement (column 34 lines 17-19). This is to synchronize any of the data of the cardiac patient.

2. Claims 15, 16, and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Valikai et al. (US Patent No. 5948005). Valikai shows a system that includes an implantable pacemaker, which records heart rate/event data. There is also an external programmer that generates (transmits) a request signal (polling signal) for the implantable device to communicate with and also has a receiving unit (receiver) that acquires data from the implantable device as well as sensed data from a physiological sensor (column 6 lines 17-32). The physiological sensor is disclosed as being coupled either within the pacemaker or just coupled outside the pacemaker (column 5 lines 32-39). The physiological sensor either way senses data such as physical activity, respiration rate, or blood oxygen level (non-implant cardiac data) (column 1 lines 58-64, column 7 lines 9-28). The external programmer is controlled by a programming code (software program) loaded in the microprocessor of the programmer (column 8 lines 8-15). The programming code allows the programmer to gather heart rate data from the implanted cardiac device (implant cardiac data) as well as physiological data acquired from the physiological sensor coupled to the implanted pacemaker (column 9 lines 38-57). The data (physiological data and implanted cardiac data) is then correlated to produce a histogram chart (signature pattern) (column 11 lines 22-67, column 12 lines

15-33, Fig. 7-8). All the data, heart rate, event, or the histogram graph can be displayed on the external programmer display (column 22 lines 50-67, column 23 10-11, column 24 lines 1-9).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 4 and 13 rejected under 35 U.S.C. 103(a) as being unpatentable over Peel, III et al. (US Patent No. 6647287) as applied to claims 1 and 10, and further in view of Stomberg et al. (US 2005/0103351). Peel, III substantially discloses the invention as claimed, however does not show a synchronization with time of data from a non-implantable medical device and data from an implantable medical device. Stomberg discloses a method using an external medical device as a reference time

when taking measurements of time with the implantable medical device (page 6 sections [0061-0063]). This is to allow for correction of a time drift that occurs in an implantable medical device. Therefore it would have been obvious to one of ordinary skill in the art, at the time of the invention, to modify the method of Peel, III by adding the time synchronization method, that uses a at least one time reference of a external medical device and a time reference of the clock in an implantable medical device, as taught by Stomberg in order to facilitate a correction of any type of time drift that can occur from a implantable medical device.

6. Claims 5 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Peel, III et al. (US Patent No. 6647287) as applied to claims 1 and 10, in view of Shimoni (US Patent No. 4616333). Peel, III substantially discloses the invention as claimed, however does not show alignment of non-implant and implant cardiac data to at least one fiducial point. Shimoni discloses a method that obtains a first set of values dealing with data (any form of data) with a certain number of points, then obtaining a second set of data (any type of data) with the same number of points as the first set, the selecting a subset of data points. Then selecting a fiducial value within the first data set and another fiducial point in the subset. Theses values are used as points for alignment with use of a calculation with the first set and the subset data points (column 2 lines 63-68 column 3 lines 6-13). Therefore it would have been obvious to one of ordinary skill in the art, at the time of the invention, to modify the method of Peel, III by adding the calculation process of two data sets with use of a fiducial point as a marker as taught by Shimoni in order to facilitate an alignment and correlation of two data sets.

7. Claims 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Valikai et al. (US Patent No. 5948005) as applied to claim 15, and further in view of Bardy (US 2002/0099302). Valikai substantially discloses the invention as claimed, however Valikai does not show the monitoring system of the patient is adapted to communicate with other devices on a network and the data can be received for the monitor from the networks other devices. Bardy discloses a system that sends data from the implantable medical device to an external medical device. The external device then sends the data to a server via an inter-network. This data is placed into a patient care file on a database (page 3 section 0032). The patient care file, on the database, can be accessed by medical devices located on the network for later use Therefore it would have been obvious to one of ordinary skill in the art, at the time of the invention, to modify the system and implantable medical device (i.e. pacemaker) of Valikai by adding the inter-network server communication to a database, as taught by Bardy in order to exchange patient data and store data on a centralized database for later use.

Response to Arguments

8. Applicant's arguments with respect to claim 20 have been considered but are moot in view of the new ground(s) of rejection.

9. Applicant's arguments filed 2/20/2007 have been fully considered but they are not persuasive. Regarding claims 1-3 and 6-12 examiner finds that the Peel reference does actually teach the step of synchronizing the non-implant cardiac data with implant cardiac data as well as generating a signature pattern of the patient. Peel discloses values from the implant in the radial or ulnar artery are synchronized with the

plethysmographic blood pressure values found from a finger sensor. By use of a mathematical model (algorithm) for correlation (column 16 lines 60-67, column 17 lines 1-3, column 18 lines 32-40), a patient-specific aortic blood pressure waveform (signature pattern) is the result from the patients' implant and non-implant cardiac data acquired (column 7 lines 37-40).

10. Applicant's arguments filed 2/20/2007 have been fully considered but they are not persuasive. Regarding claims 15-19 examiner finds that Valikai does teach means collecting non-implant data correlating the data with implant data and creating a signature pattern. A physiological sensor is disclosed as being coupled either within the pacemaker or just coupled externally from the pacemaker (column 5 lines 32-39). The physiological sensor either way senses data such as physical activity, respiration rate, or blood oxygen level (non-implant cardiac data) (column 1 lines 58-64, column 7 lines 9-28). The data (physiological data and implanted cardiac data) is then correlated to produce a histogram chart (signature pattern) that is displayed (column 11 lines 22-67, column 12 lines 15-33, Fig. 7-8).

Conclusion

The following patent and patent application publications are cited and further show the state of the art with respect to implant cardiac data and non-implant cardiac data correlation and synchronization in general:

Manolas - US 2003/0204145

Crosby et al. - US 7074194

Hirsh US - 7054679

Sahai - US 6654631

Raymond et al. - US 6640134

Ripart - US 6385485

Sohma et al. - US 6129677

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon-Eric C. Morales whose telephone number is 571-272-3107. The examiner can normally be reached on Monday through Friday from 8am - 5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Pezzuto can be reached on (571) 272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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